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(54) Title: ORAL TREATMENT SYSTEMS

(57) Abstract: The invention relates to an oral treatment system comprising two or more oral treatment compositions held within a single, hand-held, electrically powered housing. In particular, the invention relates to an electric toothbrush capable of sequentially delivering two or more oral treatment compositions integrated into the brush handle. The system provides improved oral treatment regimens.



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ORAL TREATMENT SYSTEMS

Field of the Invention

The present invention relates to an oral treatment system comprising two or more oral treatment compositions held within a single, hand-held, electrically powered housing. In particular, the invention relates to an electric toothbrush capable of sequentially delivering two or more oral treatment compositions integrated into the brush handle. The system provides improved oral treatment regimens.

Background Of The Invention

It still remains the case that most regular oral treatments are provided via the application of a single dentifrice product during tooth brushing. Such application generally relies on a user dispensing a product onto a brush head from a tube of such product. Very recently, electric toothbrushes, historically rather expensive, have become much more affordable and therefore more widespread. The basic process however, of squeezing toothpaste onto the brush head remains the same.

Whether using a manual or powered toothbrush in this way, a problem arises with placing a dentifrice on the bristles, in that there is a lack of consistency of delivery of the dentifrice. For example, the concentration of dentifrice on the bristles is at a maximum just after application of a dentifrice to the bristles, prior to brushing. Commencement of brushing quickly results in a decrease of the concentration of dentifrice on the bristles, and a possible reduction in the advantage provided by the dentifrice.

While it is possible to occasionally stop brushing, and reapply the dentifrice to the bristles, a more practical approach would be to provide the toothbrush with a reservoir from which the dentifrice is dispensed during brushing, either intermittently or continuously.

Such an idea is not new. For example, U.S. Patent No. 730,040, issued June 2, 1903 to McKinley et al., discloses a toothbrush having a receptacle for feeding a liquid dentifrice into the bristles of the brush. U.S. Patent No. 3,217,720, issued November 16, 1965 to Cyzer, discloses a toothbrush with a liquid dentifrice container. U.S. Patent 5,909,977, issued June 8, 1999 to Kuo, discloses a dentifrice dispensing toothbrush utilizing a
5 refillable cartridge for storing dentifrice material and a compressible elastic button for pumping dentifrice material to the brush head. Further development of this idea includes the use of hollow bristles through which the dentifrice flows as disclosed in U.S. Patent No. 5,309,590, issued May 10, 1994 to Giuliani et al.

- 10 A further problem with most oral treatment regimens is that they are limited to those treatments which can be provided within a single chemically stable composition, thus excluding treatment compositions which may be more efficacious but have the deficiency of being unstable on storage, or compositions whose components are best delivered sequentially.
- 15 Dual component dentifrice compositions are known in which a single product encompasses two distinct phases. Typical are those described in PCT applications WO 00/32159, WO 00/42981 and WO 99/55297. In such products, chemically incompatible components may be kept separated in distinct compartments of a flexible tube or other dispenser until dispensed onto a toothbrush, generally as two, side by side,
20 ribbons. WO 00/62748 describes an oral care system in which two distinct products are provided, e.g. as a kit, which may be applied sequentially to the oral cavity. German publications DE 198 01 111 A1 and DE 297 21 297 U1 describe manual toothbrushes with two integrated cavities in which separate products may be stored for direct dispensing onto the brush head through a connecting channel. These brushes however do
25 no permit a convenient substitution of one product for another since there is no straightforward mechanism for removal of residues of the first product when it is desired to substitute it with a second.

There remains a need therefore for an oral care system which can provide a variety of efficacious treatment regimens with the convenience expected by the modern day

consumer. These and other needs will become apparent to those of skill in the art upon review of this specification.

Summary Of The Invention

According to one embodiment of the present invention, there is provided an oral treatment system comprising a unitary housing, that can be comfortably gripped in a user's hand, the housing containing a cartridge comprising first and second reservoirs. The reservoirs respectively contain first and second, liquid, oral treatment compositions, the first and second compositions being different to each other. The system further comprises an applicator attached or attachable to the housing for applying the first and second oral treatment compositions to the teeth or oral soft tissues; an electrical power source to provide energy for pumping the compositions to the applicator and / or to supply energy to the applicator; and control means to allow the user to simultaneously or sequentially deliver the first and second compositions to the oral cavity. The system yet further comprises a set of instructions for the user.

According to a further aspect of the invention, there is provided a kit comprising a unitary cartridge adapted for use in the oral treatment system, the cartridge comprising first and second reservoirs respectively containing a first and second, liquid oral treatment compositions and a set of instructions for use of the cartridge with the system.

According to yet a further aspect of the invention, there is provided a method of treating the teeth or oral soft tissues comprising providing the oral treatment system to a user and instructing the user to actuate the control means in order to deliver the first and second treatment compositions to the user's teeth or oral soft tissues.

Detailed Description Of The Invention

The system of the present invention includes a cartridge for storing two or more liquid, oral treatment compositions. In a highly preferred embodiment the cartridge is replaceably removable from the housing, for example to allow the reservoirs to be refilled and the cartridge reinserted, for the cartridge to be replaced by one of substantially identical construction which may comprise further quantities of the same oral treatment compositions or may provide different compositions to supply a different oral treatment

regimen. A suitable housing, cartridge and applicator assembly is described in co-pending application having the US serial number 09/721431 which is incorporated herein by reference in its entirety. An applicator is attached or attachable to the housing through for applying the treatment compositions to the oral cavity. The applicator may be any
5 suitable device for applying the compositions to teeth or oral soft tissues, and includes an application surface which may be a brush or a sponge. Preferably the applicator is a brush. Suitably, one or more channels run through the applicator to provide fluid communication between the reservoirs and the application surface.

Any suitable reservoir or cartridge may be utilized in the present invention. It should be
10 understood that the reservoir or cartridge utilized may be fully or partially internal to the housing, or fully or partially external to the housing. Non-limiting examples of suitable reservoirs include positive displacement type reservoirs that are generally rigid-walled such as a cartridge, and also include pump-evacuated type reservoirs that are generally soft-walled such as sachets, bladders, and blisters.

15 An electrical power source is provided within the housing to provide energy for pumping the compositions to the applicator and / or to supply energy to the applicator, for example to drive a movable brush head. The power source can also be used to provide sonic energy to the compositions, as described in U.S. Patent No. 5,309,590, issued May 10, 1994 to Giuliani et al., incorporated herein by reference.

20 Control means, such as a switch or set of switches, optionally associated with a suitable microprocessor, allow the user to simultaneously or sequentially deliver the first and second compositions to the oral cavity. The use of a microprocessor is preferred since, by this means, precise, controlled dosage of treatment compositions can be achieved, or complex treatment regimens delivered. The microprocessor can be preprogrammed or
25 programmable. Of course, to enhance oral care this microprocessor could be programmed to provide alarms or messages to a small display screen to remind the user to dispense certain compositions at certain times. For example, for two oral treatments where one is to be dispensed from the first reservoir every 4 hours, the other to be dispensed from the second reservoir every six hours, the microprocessor could be programmed to so
30 dispense, with reminders/alarms to the user to use the brush at the appropriate times.

With or without a microprocessor, the ability to select simultaneous or sequential treatments from the two or more reservoirs allows for a wide variety of oral treatment regimens.

5 It is even envisioned that a given pre-loaded cartridge may further include its own executable instructions on a medium (for example a small chip, disk, microprocessor, or Radio Frequency ID tag to activate proprietary program functions) that is loaded into the housing to dispense material from the cartridge reservoirs as desired.

10 Necessarily, for an oral treatment system this complex a set of instructions needs to be provided for the user. Typically this would be done by the enclosure of a separate leaflet or small booklet enclosed with the system as part of a kit. A part of the instruction set could be integrated into the system via a microprocessor which communicates with the user via, for example, a LCD display screen, for example to give a simple instruction such as 'Now Select Switch B' or 'Battery replacement required'. The instructions may provide advice on the selection of the first and second compositions, according to the user's oral care needs. These instructions may relate solely to the use of the compositions present in the system on purchase, or may extend to advice on which auxiliary compositions to use, such as the selection of a replacement cartridge. The instructions may further provide advice on a treatment regimen to be applied with the system, according to the user's oral care needs, for example advice on what times of day to use the system and what treatments to select.

25 In yet a further embodiment of the invention, provision may be made for in situ refilling of the reservoirs contained within the housing from a separate refill cartridge, external to the housing, which is further provided with the system. This can be advantageous where the volumes of composition consumed during treatments are relatively large and it would be costly or wasteful to throw away an internal cartridge each time it was emptied. The external refill cartridge may form part of a base station that additionally performs the function of recharging a rechargeable battery within the housing.

Treatment Compositions

- A wide variety of treatment compositions can be provided for use with the system. Preferably, a first treatment composition includes a cleaning agent. Typically such a composition comprises from 0.1 to 40% of a cleaning agent selected from surfactants; abrasives and mixtures thereof. A wide variety of surfactants and abrasives is known in the art for oral care. Preferred surfactant levels are from 0.1% to 5%, more preferably from 0.5% to 5%. All percentages quoted herein are by weight of the respective treatment composition. Preferred abrasive levels are from 5% to 40%, more preferably from 5% to 25%. Suitable abrasives include calcium carbonate, precipitated silicas and insoluble phosphates.
- Other preferred oral treatment compositions comprises from 0.01 to 20% of a conditioning agent selected from animal oils, mineral oils, vegetable oils and silicone oils, polymers which are substantive to the surfaces of the teeth or oral soft tissues; and mixtures thereof. A suitable vegetable oil is sunflower oil. Preferred conditioning agents are silicone oils. Suitable classes of silicone oils include, but are not limited to, dimethicones, dimethiconols, dimethicone copolyols and aminoalkylsilicones. More detail of these materials is provided in WO97/17939. Preferred aminoalkylsilicones comprise amodimethicones, such as OSI's Magnasoft® fluid. More preferred for use herein are alkyl- and alkoxy-dimethicone copolyols and mixtures thereof. Especially preferred are the dimethicone copolyols disclosed in WO96/33693, incorporated herein by reference. Such dimethicone copolyols have utility as antiplaque agents. In preferred embodiments, the dimethicone copolyol is selected from C₁₂ to C₂₀ alkyl dimethicone copolyols and mixtures thereof. Highly preferred is cetyl dimethicone copolyol marketed under the Trade Name Abil EM90.
- Preferably at least one of the first and second treatment compositions comprises a fluoride ion source. Non-limiting examples of suitable fluoride ion sources include stannous fluoride, sodium fluoride, and sodium monofluorophosphate. The preferred fluoride ion source is sodium fluoride. Preferred compositions comprises a fluoride ion source providing from 100 to 3000 ppm of fluoride ion.

Other suitable oral treatment composition components include solvents, diluents, thickening agents, and the like to provide support for the treatment composition while dispensed on the applicator surface.

Yet further useful components include antimicrobials such as triclosan; anticalculus agents such as tetrasodium and tetrapotassium pyrophosphates and the polyphosphates disclosed in WO 98/22079; humectants, sweeteners and flavoring oils. All these components can be used at their art known levels.

The oral treatment compositions of the present invention will preferably have a viscosity amenable to pumping from the reservoirs to the applicator surface whilst avoiding being too thin so that the composition runs out of the applicator before use.

As used herein, the term "viscosity" refers to "dynamic viscosity" and is defined as the ratio of the shearing stress to the rate of deformation. A preferred viscosity for the first and second oral treatment compositions is from about 10 to about 500 Pa.s when measured at a shear rate of 0.1 s^{-1} at 25°C . These viscosities encompass both pourable liquids and gels which can be made to flow under a shear stress.

Treatment Regimens

The system can deliver two compositions entirely simultaneously. This is advantageous where different chemical components are required simultaneously but cannot be stably stored together in one composition. General examples here would include an active ingredient and an activator for the ingredient. Specific examples here include the many peroxide whitening treatments known in the art, such as those disclosed in WO 98/31331.

In preferred embodiments the first and second treatment compositions are delivered sequentially to the teeth or oral soft tissues. The first and second treatment compositions can be delivered within the same treatment occasion, such as when both are both delivered within a period of five minutes. In these instances the timing of delivery of the two compositions may overlap provided that one treatment starts before or finishes after the other. Preferably the two treatments are cleanly separated so that there is no simultaneous delivery. A suitable treatment regimen here includes a first cleaning

treatment followed immediately by a second conditioning treatment which may provide a protective coating to prevent plaque build up through the day.

Alternately there may be a substantial intervening rest period between the delivery of the first and second compositions. A suitable rest period could be at least six hours, for example when one composition is delivered in a morning treatment and another is delivered in an evening treatment. Usage instructions for this type of regimen may include means for reminding the user which composition is to be used. A suitable means may be a card based switch which the user resets after each usage. Alternately microprocessor control may alert the user via a visual display or audible indication (such as different tones) or may entirely automate the process. A suitable treatment regimen here may include a cleaning treatment in the morning, perhaps with only the first composition being delivered, succeeded by an evening treatment in which the cleaning composition is again delivered first but is then followed immediately by a second specialist remineralisation treatment for intensive overnight action.

15 Examples

Formula 1A is a cleaning composition useful in the present invention.

1A

<u>Ingredient</u>	<u>% Wt/Wt</u>
Sorbitol (70%), low reducing sugars	60.0
Glycerin	10.0
Xanthan gum	0.5
Sodium fluoride	0.24
Sodium saccharin	0.3
Flavour	1.5
Triclosan	0.28
Sodium lauryl sulphate solution (28%)	8.0
PEG-6	4.0
Hydrated silica, amorphous	10.0
Water	to 100%

Formula 1B is a moisturising composition useful for night time use.

1B

<u>Ingredient</u>	<u>% Wt/Wt</u>
Glycerin	30.0

Xylitol	20.0
Xanthan gum	0.5
Sodium fluoride	0.24
Sodium benzoate	0.1
Titanium dioxide	0.5
Sodium saccharin	0.3
Flavour	1.0
Betaine	4.0
Sodium lauryl sulphate solution (28%)	4.0
Hydrated silica, amorphous	10.0
Water	to 100%

Formulae 1A and 1B are provided in separate reservoirs within the system, which is fitted with an applicator brush, and the user is provided with instructions to actuate control switches in order to deliver Formula 1A during morning brushing and Formula 1B for night-time brushing.

- 5 Optionally, the system may be provided with an alternate cartridge containing Formula 1A in the first reservoir and a mineralising gel comprising a substantive fluoride treatment in the second reservoir so that Formula 1A is delivered during morning brushing and the fluoride treatment is delivered during night-time brushing. Sonic energy is delivered to the treatment compositions during each brushing occasion.
- 10 While the illustrative embodiments of the invention have been described with particularity, it will be understood that various other modifications will be apparent to and can be readily made by those skilled in the art without departing from the spirit and scope of the invention. Accordingly, it is not intended that the scope of the claims appended hereto be limited to the examples and descriptions set forth herein but rather that the
- 15 claims be construed as encompassing all the features of patentable novelty which reside in the present invention, including all features which would be treated as equivalents thereof by those skilled in the art to which this invention pertains. In particular, whilst the examples imply a system which encompasses two treatment composition reservoirs within a cartridge, more complex cartridges which contain three, four or more reservoirs
- 20 may be envisaged.

Claims

1. An oral treatment system comprising:
 - (a) a unitary housing, that can be comfortably gripped in a user's hand, the housing containing a cartridge comprising:
 - (i) a first reservoir containing a first, liquid oral treatment composition;
 - (ii) a second reservoir containing a second, liquid oral treatment composition, which is different to the first oral treatment composition;
 - (b) an applicator attached or attachable to the housing for applying the first and second oral treatment compositions to the teeth or oral soft tissues;
 - (c) an electrical power source to provide energy for pumping the compositions to the applicator and / or to supply energy to the applicator;
 - (d) control means to allow the user to simultaneously or sequentially deliver the first and second compositions to the oral cavity; and
 - (e) a set of instructions for the user.
2. A system of Claim 1 wherein the first and second reservoirs are replaceably removable from the housing.
3. A system of Claim 1 or Claim 2 wherein an oral treatment composition comprises from 0.1 to 40% of a cleaning agent selected from surfactants; abrasives and mixtures thereof.
4. A system according to any preceding claim wherein an oral treatment composition comprises from 0.01 to 20% of a conditioning agent selected from animal oils, mineral oils, vegetable oils and silicone oils, polymers which are substantive to the surfaces of the teeth or oral soft tissues; and mixtures thereof.
5. A system according to any preceding claim wherein an oral treatment composition comprises a fluoride ion source providing from 100 to 3000 ppm of fluoride ion.

6. A system according to any preceding claim wherein the first and second oral treatment compositions have a viscosity of from 10 to 500 Pa.s when measured at a shear rate of 0.1 s^{-1} at 25°C .
7. A system according to any preceding claim which comprises means for applying sonic energy to one or more of the treatment compositions.
8. A system according to any preceding claim wherein the instructions provide advice on the selection of the first and second compositions, according to the user's oral care needs.
9. A system according to any preceding claim wherein the instructions provide advice on a treatment regimen to be applied with the system, according to the user's oral care needs.
10. A kit comprising a unitary cartridge adapted for use in an oral treatment system according to any preceding claim, the cartridge comprising
 - (a) first and second reservoirs respectively containing a first and second, liquid oral treatment compositions;
 - (b) a set of instructions for use of the cartridge with the system.
11. A method of treating teeth or oral soft tissues comprising providing an oral treatment system according to any preceding claim to a user and instructing the user to actuate the control means in order to deliver the first and second treatment compositions to the user's teeth or oral soft tissues.
12. A method according to Claim 11 wherein the first and second treatment compositions are delivered sequentially.
13. A method according to Claim 12 wherein the first and second treatment compositions are both delivered within a period of five minutes.
14. A method according to Claim 12 wherein the first and second treatment compositions are delivered with an intervening rest period of at least six hours.

INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61C17/34 A46B13/04 A46B11/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61C A46B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 321 866 A (KLUP T MICHAEL F) 21 June 1994 (1994-06-21) the whole document ----	1-14
A	WO 92 10146 A (GEMTECH INC) 25 June 1992 (1992-06-25) the whole document ----	1-14
A	DE 197 17 868 A (SCHOERKMAYR JOSEF B) 29 October 1998 (1998-10-29) the whole document -----	1-14



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

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Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

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INTERNATIONAL SEARCH REPORT
information on patent family members

Int'l Application No
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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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